UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

SCILEX PHARMACEUTICALS INC., ITOCHU CHEMICAL FRONTIER CORPORATION, AND OISHI KOSEIDO CO., LTD., Plaintiffs, v. AVEVA DRUG DELIVERY SYSTEMS, INC., APOTEX CORP., AND APOTEX INC., Defendants.	Civil Action No. _____

COMPLAINT

Plaintiffs Scilex Pharmaceuticals Inc., ITOCHU CHEMICAL FRONTIER Corporation, and Oishi Koseido Co., Ltd. (collectively "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendant Aveva Drug Delivery Systems, Inc. of an Abbreviated New Drug Application ("ANDA") No. 217221 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a Lidocaine Topical System, 1.8% product ("Aveva's ANDA Product"), a generic version of Scilex Pharmaceuticals Inc.'s ZTLIDO® (lidocaine topical system) 1.8% ("ZTlido®"), prior to the expiration of U.S. Patent Nos. 9,283,174 (the "'174 patent"), 9,925,264 (the "'264 patent"), and 9,931,403 (the "'403 patent") (collectively "the Asserted Patents"). Aveva Drug Delivery Systems, Inc. notified Scilex Pharmaceuticals Inc., ITOCHU CHEMICAL FRONTIER Corporation, and Oishi Koseido Co.,

Ltd. that it had submitted this ANDA by a letter dated May 10, 2022 (the "Notice Letter"). Upon information and belief, Aveva's ANDA Product will be marketed as a generic competing product to ZTlido®, a product developed by Plaintiffs for the relief of pain associated with post-herpetic neuralgia (PHN) in adults.

PARTIES

2. Scilex Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and place of business at 960 San Antonio Road, Palo Alto, CA 94303.

3. ITOCHU CHEMICAL FRONTIER Corporation is a company organized and existing under the laws of Japan, with its principal place of business located at 16th Floor, Itochu Bldg., 5-1, Kita-Aoyama 2-chome, Minato-ku, Tokyo 107-0061, Japan.

4. Oishi Koseido Co., Ltd. is a company organized and existing under the laws of Japan, with its principal place of business located at 1-933, Hon-Machi 1-Chome, Tosu, Saga 841-0037, Japan.

5. On information and belief, Aveva Drug Delivery Systems, Inc. is a corporation organized and existing under the laws of the State of Florida, having its principal place of business at 3250 Commerce Park Way, Miramar, FL 33025 with packaging operations at 2400 N. Commerce Parkway, Suite 400, Weston, FL 33326.

6. On information and belief, Aveva Drug Delivery Systems, Inc. is a majority-owned subsidiary of Apotex Inc.

7. On information and belief, Apotex Corp. is a Delaware corporation having a principal place of business at 2400 N. Commerce Parkway, Suite 400, Weston, FL 33326.

8. On information and belief, Apotex Corp. is a majority-owned subsidiary of Apotex Inc.

9. On information and belief, Apotex Inc. is a company organized and existing under the laws of Canada, with its principal place of business located at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

10. On information and belief, Aveva Drug Delivery Systems, Inc., Apotex Corp., and Apotex Inc. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products in the United States. On further information and belief, Aveva Drug Delivery Systems, Inc., Apotex Corp., and Apotex Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. This Court has personal jurisdiction over Aveva Drug Delivery Systems, Inc. Upon information and belief, Aveva Drug Delivery Systems, Inc. is incorporated in the State of Florida. Upon information and belief, Aveva Drug Delivery Systems, Inc. is engaged in developing, manufacturing, marketing, selling, and distributing transdermal pharmaceutical products globally. Upon information and belief, a substantial number of these products are marketed throughout the United States, including in the State of Florida. Upon information and belief, Aveva Drug Delivery Systems, Inc. purposefully operates its manufacturing, marketing, sales, and distribution infrastructure in the United States either itself or via corporate parents, subsidiaries, and affiliates as a vertically integrated company.

13. This Court has personal jurisdiction over Apotex Corp. Upon information and belief, Apotex Corp. maintains its principal place of business at 2400 N. Commerce Parkway, Suite 400, Weston, FL 33326. Upon information and belief, Apotex Corp. is engaged in developing, manufacturing, marketing, selling, and distributing a broad range of generic pharmaceutical products globally. Upon information and belief, a substantial number of these products are marketed throughout the United States, including in the State of Florida. Upon information and belief, Apotex Corp. purposefully operates its manufacturing, marketing, sales, and distribution infrastructure in the United States either itself or via corporate parents, subsidiaries, and affiliates as a vertically integrated company.

14. This Court has personal jurisdiction over Apotex Inc. Upon information and belief, Apotex Inc. itself, and through its majority-owned subsidiaries Apotex Corp. and Aveva Drug Delivery Systems, Inc., is engaged in developing, manufacturing, marketing, selling, and distributing a broad range of generic pharmaceutical products globally. Upon information and belief, a substantial number of these products are marketed throughout the United States, including in the State of Florida. Upon information and belief, Apotex Inc. purposefully operates its manufacturing, marketing, sales, and distribution infrastructure in the United States either itself or via corporate parents, subsidiaries, and affiliates as a vertically integrated company. In addition, Apotex Inc. is subject to personal jurisdiction in Florida because, on information and belief, it controls Apotex Corp. and Aveva Drug Delivery Systems, Inc., and therefore the activities of Apotex Corp. and Aveva Drug Delivery Systems, Inc. in this jurisdiction are attributable to Apotex Inc.

15. Alternatively, if the exercise of personal jurisdiction over Apotex Inc. in this Court is not held to be proper, then, upon information and belief, Apotex Inc. is not subject to jurisdiction

in any state's courts of general jurisdiction, and therefore personal jurisdiction over Apotex Inc. in this Court is proper pursuant to Fed. R. Civ. P. 4(k)(2).

16. Upon information and belief, Aveva Drug Delivery Systems, Inc., Apotex Corp., and Apotex Inc. (collectively "the Aveva Defendants") hold themselves out as a unitary entity and operate as a single integrated business with regard to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in the State of Florida.

17. Upon information and belief, Apotex Corp. and Apotex Inc. have been sued in this judicial district without challenging personal jurisdiction and have availed themselves of the legal protections of the State of Florida by filing claims or counterclaims affirmatively seeking relief in other prior actions in this Court, including *UCB, Inc. et al. v. Apotex Inc.*, No. 0:18-cv-60846-MGC, D.I. 16 at 3–4 (S.D. Fla. May 10, 2018); *Amgen Inc. et al. v. Apotex Inc. et al.*, No. 0:15-cv-61631-JIC, D.I. 47 at 5 (S.D. Fla. Oct. 23, 2015). In addition, Apotex Corp. and Apotex Inc. have previously submitted to this Court's jurisdiction and previously availed themselves of this Court by filing suit in this jurisdiction and/or by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Apotex Inc. et al. v. Teva Pharmaceutical Industries, Ltd. et al.*, No. 0:13-cv-60601-PAS (S.D. Fla. filed Mar. 14, 2013); *Apotex Inc. et al. v. Mylan Pharmaceuticals, Inc.*, No. 0:12-cv-60704-PAS (S.D. Fla. filed Apr. 20, 2012). Further, Apotex Inc. and Apotex Corp. have previously admitted that this Court has personal jurisdiction over both Apotex Corp. and Apotex Inc. *See Alcon Manufacturing, Ltd. et al. v. Apotex Inc. et al.*, No. 1:06-cv-01642-RLY-TAB, D.I. 23 at 7 (S.D. Ind. Dec. 13, 2006) ("Plaintiffs could have brought this action in the S.D.Fla. because the S.D.Fla. has personal jurisdiction over both Defendants[.] Apotex Corp. has a principal place of business in Weston, Florida, while Apotex Inc. is a Canadian

corporation that regularly conducts business in Florida. Thus, venue in the S.D.Fla. would also be proper.").

18. Upon information and belief, the Aveva Defendants regularly do business in Florida and have engaged in a persistent course of conduct within Florida by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Florida, and/or by directly selling pharmaceutical products in Florida.

19. Upon information and belief, Aveva Drug Delivery Systems, Inc. has sought approval in ANDA No. 217221 to distribute Aveva's ANDA Product in the United States, including in Florida and will do so upon approval of ANDA No. 217221. The filing of ANDA No. 217221 is therefore tightly tied, in purpose and planned effect, to the deliberate making of sales in Florida, and reliably indicates that the Aveva Defendants plan to engage in the marketing of Aveva's ANDA Product in this State.

20. Upon information and belief, the preparation and submission of ANDA No. 217221 was performed by the Aveva Defendants in the Southern District of Florida.

21. Upon information and belief, with knowledge of the processes described in the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b) and the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch Waxman Act"), Aveva Drug Delivery Systems, Inc. sent its Notice Letter, dated May 10, 2022, to Scilex Pharmaceuticals Inc., ITOCHU CHEMICAL FRONTIER Corporation and Oishi Koseido Co., Ltd., and alleged in the Notice Letter the invalidity, unenforceability, and/or non-infringement of the Asserted Patents. Scilex Pharmaceuticals Inc. received the Notice Letter on or after May 11, 2022. Upon information and belief, the Aveva Defendants deliberately challenged Plaintiffs' patent rights with the Notice

Letter and knew when it did so that it was triggering a forty-five-day period for Plaintiffs to bring an action for patent infringement under the FDCA.

22. Because ZTlido® is marketed, sold, and distributed throughout the United States, including in the State of Florida, the injury and consequences of the Aveva Defendants' filing of ANDA No. 217221, challenging Plaintiffs' patent rights, are suffered in Florida. Upon information and belief, the Aveva Defendants knew that they were deliberately challenging intellectual property held in Florida and that the effects of any successful challenge of the Asserted Patents would be felt by Plaintiffs in Florida.

23. Upon information and belief, if the ANDA No. 217221 is approved, the Aveva Defendants will directly or indirectly market and/or sell Aveva's ANDA Product within the United States, including in Florida, consistent with the Aveva Defendants' practices for the marketing and distribution of other pharmaceutical products on their own or through their affiliates. Upon information and belief, the Aveva Defendants and/or their affiliates regularly do business in Florida, and their practices with other pharmaceutical products have involved the distribution of the Aveva Defendants' products, directly or indirectly, throughout the United States, including in Florida. Upon information and belief, the Aveva Defendants' pharmaceutical products are used and/or consumed within and throughout the United States, including Florida.

24. Upon information and belief, the Aveva Defendants and their affiliates derive substantial revenue from pharmaceutical products that are used and/or consumed within Florida, and which are manufactured by the Aveva Defendants or their affiliates and/or for which the Aveva Defendants are the named applicant on approved ANDAs. Upon information and belief, various products for which the Aveva Defendants are the named applicant on approved ANDAs are available at pharmacies in Florida.

25. Upon information and belief, if ANDA No. 217221 is approved, Aveva's ANDA Product, under the direction and control of physicians practicing in Florida, will be administered to patients in Florida. These activities, as well as the Aveva Defendants' marketing, selling, and/or distributing of Aveva's ANDA Product, would have a substantial effect within Florida and would constitute infringement of the Asserted Patents in the event that Aveva's ANDA Product is approved before the Asserted Patents expire.

26. For the reasons described above, among others, the filing of ANDA No. 217221 was suit-related conduct with a substantial connection to Florida and this District, the exercise of personal jurisdiction over the Aveva Defendants does not offend traditional notions of fair play and substantial justice, and this Court may properly exercise personal jurisdiction over the Aveva Defendants.

27. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Aveva Drug Delivery Systems, Inc. is incorporated in the State of Florida.

28. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Apotex Corp. is a Delaware corporation having a principal place of business at 2400 N. Commerce Parkway, Suite 400, Weston, FL 33326 and has participated in acts of infringement in this district, including preparation and filing of ANDA No. 217221.

29. Upon information and belief and based on the foregoing, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Apotex Inc. is a foreign entity incorporated in Canada and may be sued in any judicial district in the United States.

BACKGROUND

30. Ztlido® is indicated for the relief of pain associated with post-herpetic neuralgia (PHN) in adults.

31. Scilex Pharmaceuticals Inc., the holder of approved New Drug Application ("NDA") No. 207962 for Ztlido®. Ztlido® is manufactured for Scilex Pharmaceuticals Inc. and is sold in the United States pursuant to NDA No. 207962.

32. The '174 patent, titled "Non-Aqueous Patch," was duly and legally issued on March 15, 2016. A copy of the '174 patent is attached as Exhibit A.

33. The '174 patent is assigned to ITOCHU CHEMICAL FRONTIER Corporation and Oishi Koseido Co., Ltd.

34. Scilex Pharmaceuticals Inc. is the exclusive licensee of the '174 patent.

35. An actual case or controversy exists between Plaintiffs and the Aveva Defendants with respect to infringement of the '174 patent.

36. The '264 patent, titled "Non-Aqueous Patch," was duly and legally issued on March 27, 2018. A copy of the '264 patent is attached as Exhibit B.

37. The '264 patent is assigned to ITOCHU CHEMICAL FRONTIER Corporation and Oishi Koseido Co., Ltd.

38. Scilex Pharmaceuticals Inc. is the exclusive licensee of the '264 patent.

39. An actual case or controversy exists between Plaintiffs and the Aveva Defendants with respect to infringement of the '264 patent.

40. The '403 patent, titled "Non-Aqueous Patch," was duly and legally issued on April 3, 2018. A copy of the '403 patent is attached as Exhibit C.

41. The '403 patent is assigned to ITOCHU CHEMICAL FRONTIER Corporation and Oishi Koseido Co., Ltd.

42. Scilex Pharmaceuticals Inc. is the exclusive licensee of the '403 patent.

43. An actual case or controversy exists between Plaintiffs and the Aveva Defendants with respect to infringement of the '403 patent.

COUNT I
(Infringement of the '174 Patent Under 35 U.S.C. § 271(e)(2))

44. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

45. Claim 1 of the '174 patent covers "[a] non-aqueous patch comprising 0.5 to 7 mass % lidocaine and/or its reactant, and a dissolving agent consisting of an organic acid and a polyalcohol, which are contained in a plaster, wherein the amount of lidocaine and/or its reactant is 0.1 to 1 mg/cm2 of the plaster, and wherein the proportion of dissolving agent to lidocaine and/or its reactant is 0.5 to 5 mass % of dissolving agent relative to 1 mass % of lidocaine and/or its reactant."

46. Upon information and belief, Aveva's ANDA product is covered by one or more claims of the '174 patent, including at least claim 1.

47. Upon information and belief, the formulation of Aveva's ANDA product comprises components that perform substantially the same function, in substantially the same way, to achieve the same result as the claimed formulation. Upon information and belief, any differences between the formulation of Aveva's ANDA product and the asserted claims are merely insubstantial.

48. Upon information and belief, Aveva's ANDA Product and its use in accordance with and as directed by Aveva's proposed labeling for that product will infringe one or more claims of the '174 patent, including at least claim 1, either literally or under the doctrine of equivalents.

49. Upon information and belief, Aveva Drug Delivery Systems, Inc., acting in concert with the other Aveva Defendants, filed as part of ANDA No. 217221 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. §355(b)(2)(A)(iv), asserting that

the claims of the '174 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Aveva's ANDA Product.

50. The purpose of filing ANDA No. 217221 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Aveva's ANDA Product prior to the expiration of the '174 patent.

51. Aveva Drug Delivery Systems, Inc.'s submission of ANDA No. 217221 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Aveva's ANDA Product prior to the expiration of the '174 patent is an act of infringement of the '174 patent under 35 U.S.C. § 271(e)(2)(A).

52. Upon information and belief, the Aveva Defendants intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aveva's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217221 and any amendments thereto, i.e., prior to the expiration of the '174 patent.

53. Upon information and belief, the Aveva Defendants have knowledge of the claims of the '174 patent at least because the '174 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Scilex Pharmaceuticals Inc.'s ZTlido® drug product. Notwithstanding this knowledge, the Aveva Defendants continue to assert their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aveva's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217221 and any amendments thereto.

54. The foregoing actions by the Aveva Defendants constitute and/or will constitute infringement of the '174 patent.

55. Unless the Aveva Defendants are enjoined from infringing the '174 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the '264 Patent Under 35 U.S.C. § 271(e)(2))

56. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

57. Claim 1 of the '264 patent covers "[a] method of treating pain in a human comprising applying a non-aqueous patch to the human the non-aqueous patch comprising 0.5 to 7 mass % lidocaine, and a dissolving agent consisting essentially of an organic acid and a polyalcohol, which are contained in a plaster, wherein the amount of lidocaine is 0.1 to 1 mg/cm2 of the plaster, and wherein the proportion of dissolving agent to lidocaine is 0.5 to 5 mass % of dissolving agent relative to 1 mass % of lidocaine."

58. Upon information and belief, Aveva's ANDA product is covered by one or more claims of the '264 patent, including at least claim 1.

59. Upon information and belief, the formulation of Aveva's ANDA product comprises components that perform substantially the same function, in substantially the same way, to achieve the same result as the claimed formulation. Upon information and belief, any differences between the formulation of Aveva's ANDA product and the asserted claims are merely insubstantial.

60. Upon information and belief, Aveva's ANDA Product and its use in accordance with and as directed by Aveva's proposed labeling for that product will infringe one or more claims of the '264 patent, including at least claim 1, either literally or under the doctrine of equivalents.

61. Upon information and belief, Aveva Drug Delivery Systems, Inc., acting in concert with the other Aveva Defendants, filed as part of ANDA No. 217221 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. §355(b)(2)(A)(iv), asserting that

the claims of the '264 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Aveva's ANDA Product.

62. The purpose of filing ANDA No. 217221 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Aveva's ANDA Product prior to the expiration of the '264 patent.

63. Aveva Drug Delivery Systems, Inc.'s submission of ANDA No. 217221 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Aveva's ANDA Product prior to the expiration of the '264 patent is an act of infringement of the '264 patent under 35 U.S.C. § 271(e)(2)(A).

64. Upon information and belief, the Aveva Defendants intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aveva's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217221 and any amendments thereto, i.e., prior to the expiration of the '264 patent.

65. Upon information and belief, the Aveva Defendants have knowledge of the claims of the '264 patent at least because the '264 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Scilex Pharmaceuticals Inc.'s ZTlido® drug product. Notwithstanding this knowledge, the Aveva Defendants continue to assert their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aveva's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217221 and any amendments thereto.

66. Upon information and belief, the Aveva Defendants plan and intend to, and will, actively induce infringement of the '264 patent, including at least claim 1, when ANDA No. 217221 and any amendments thereto are approved and will do so with specific intent to induce

infringement of the '264 patent under 35 U.S.C. § 271(b). Further upon information and belief, the Aveva Defendants plan and intend to, and will, do so immediately and imminently upon approval.

67. Upon information and belief, the Aveva Defendants know that Aveva's ANDA Product is especially made or adapted for use in infringing the '264 patent, and that Aveva's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, the Aveva Defendants plan and intend to, and will, contribute to infringement of the '264 patent, including at least claim 1, under 35 U.S.C. § 271(c) immediately and imminently upon approval of ANDA No. 217221 and any amendments thereto.

68. The foregoing actions by the Aveva Defendants constitute and/or will constitute infringement of the '264 patent, active inducement of infringement of the '264 patent, and contribution to the infringement by others of the '264 patent.

69. Unless the Aveva Defendants are enjoined from infringing the '264 patent, actively inducing infringement of the '264 patent, and contributing to the infringement by others of the '264 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III
(Infringement of the '403 Patent Under 35 U.S.C. § 271(e)(2))

70. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

71. Claim 1 of the '403 patent covers "[a] non-aqueous patch comprising 0.5 to 7 mass % lidocaine, and a dissolving agent consisting essentially of an organic acid and a polyalcohol, which are contained in a plaster, wherein the amount of lidocaine is 0.1 to 1 mg/cm2 of the plaster, and wherein the proportion of dissolving agent to lidocaine is 0.5 to 5 mass % of dissolving agent relative to 1 mass % of lidocaine."

72. Upon information and belief, Aveva's ANDA product is covered by one or more claims of the '403 patent, including at least claim 1.

73. Upon information and belief, the formulation of Aveva's ANDA product comprises components that perform substantially the same function, in substantially the same way, to achieve the same result as the claimed formulation. Upon information and belief, any differences between the formulation of Aveva's ANDA product and the asserted claims are merely insubstantial.

74. Upon information and belief, Aveva's ANDA Product and its use in accordance with and as directed by Aveva's proposed labeling for that product will infringe one or more claims of the '403 patent, including at least claim 1, either literally or under the doctrine of equivalents.

75. Upon information and belief, Aveva Drug Delivery Systems, Inc., acting in concert with the other Aveva Defendants, filed as part of ANDA No. 217221 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. §355(b)(2)(A)(iv), asserting that the claims of the '403 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Aveva's ANDA Product.

76. The purpose of filing ANDA No. 217221 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Aveva's ANDA Product prior to the expiration of the '403 patent.

77. Aveva Drug Delivery Systems, Inc.'s submission of ANDA No. 217221 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Aveva's ANDA Product prior to the expiration of the '403 patent is an act of infringement of the '403 patent under 35 U.S.C. § 271(e)(2)(A).

78. Upon information and belief, the Aveva Defendants intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aveva's

ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217221 and any amendments thereto, i.e., prior to the expiration of the '403 patent.

79. Upon information and belief, the Aveva Defendants have knowledge of the claims of the '403 patent at least because the '403 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Scilex Pharmaceuticals Inc.'s ZTlido® drug product. Notwithstanding this knowledge, the Aveva Defendants continue to assert their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aveva's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 217221 and any amendments thereto.

80. The foregoing actions by the Aveva Defendants constitute and/or will constitute infringement of the '403 patent.

81. Unless the Aveva Defendants are enjoined from infringing the '403 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV
(Declaratory Judgment of Patent Infringement of the '174 Patent Under 35 U.S.C. § 271 (a))

82. Plaintiffs reallege and incorporate each of the preceding paragraphs as if fully set forth herein.

83. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.,* including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

84. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Aveva's ANDA Product, if approved by the FDA, will infringe either literally or under the doctrine of equivalents one or more claims of the '174 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights.

85. Upon information and belief, the formulation of Aveva's ANDA product comprises components that perform substantially the same function, in substantially the same way, to achieve the same result as the claimed formulation. Upon information and belief, any differences between the formulation of Aveva's ANDA product and the asserted claims are merely insubstantial.

86. Upon information and belief, the Aveva Defendants have knowledge of the '174 patent and Aveva Drug Delivery Systems, Inc. has filed ANDA No. 217221 seeking authorization to commercially manufacture, use, offer for sale, and sell Aveva's ANDA Product in the United States. Upon information and belief, if the FDA approves ANDA No. 217221, physicians, health care providers, and/or patients will use Aveva's ANDA Product in accordance with the instructions and/or label provided by the Aveva Defendants and will directly infringe, either literally or through the doctrine of equivalents, one or more claims of the '174 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights.

87. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and the Aveva Defendants as to liability for the infringement of '174 patent claims. The Aveva Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from the Aveva Defendants' threatened imminent actions.

COUNT V
(Declaratory Judgment of Patent Infringement of the '264 Patent Under 35 U.S.C. § 271 (b), and/or (c))

88. Plaintiffs reallege and incorporate each of the preceding paragraphs as if fully set forth herein.

89. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.,* including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

90. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Aveva's ANDA Product, if approved by the FDA, will infringe either literally or under the doctrine of equivalents one or more claims of the '264 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights.

91. Upon information and belief, the formulation of Aveva's ANDA product comprises components that perform substantially the same function, in substantially the same way, to achieve the same result as the claimed formulation. Upon information and belief, any differences between the formulation of Aveva's ANDA product and the asserted claims are merely insubstantial.

92. Upon information and belief, the Aveva Defendants have knowledge of the '264 patent and Aveva Drug Delivery Systems, Inc. has filed ANDA No. 217221 seeking authorization to commercially manufacture, use, offer for sale, and sell Aveva's ANDA Product in the United States. Upon information and belief, if the FDA approves ANDA No. 217221, physicians, health care providers, and/or patients will use Aveva's ANDA Product in accordance with the instructions and/or label provided by the Aveva Defendants and will directly infringe, either literally or through the doctrine of equivalents, one or more claims of the '264 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights.

93. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Aveva's ANDA Product so labeled, if approved by the FDA, will induce, and contribute to the infringement of one or more claims of the '264 patent, including at least claim 1, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs' patent rights.

94. Upon information and belief, the Aveva Defendants know and intend that physicians, health care providers, and/or patients will use Aveva's ANDA Product in accordance

with the instructions and/or label provided by the '264 patent, including at least claim 1, with the requisite intent under 35 U.S.C. § 271(b).

95. Upon information and belief, if the FDA approves ANDA No. 217221, the Aveva Defendants will sell or offer to sell Aveva's ANDA Product specifically labeled for use in practicing one or more claims of the '264 patent, including at least claim 1, wherein Aveva's ANDA Product is a material part of the invention claimed in the '264 patent, wherein the Aveva Defendants know that physicians will prescribe and patients will use Aveva's ANDA Product for practicing one or more claims in the '264 patent, and wherein Aveva's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, the Aveva Defendants will thus contribute to the infringement of the '264 patent under 35 U.S.C. § 271(c).

96. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and the Aveva Defendants as to liability for the infringement of '264 patent claims. The Aveva Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from the Aveva Defendants' threatened imminent actions.

COUNT VI
(Declaratory Judgment of Patent Infringement of the '403 Patent Under 35 U.S.C. § 271 (a))

97. Plaintiffs reallege and incorporate each of the preceding paragraphs as if fully set forth herein.

98. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.,* including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

99. Upon information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Aveva's ANDA Product, if approved by the FDA, will infringe either literally or under the doctrine of equivalents one or more claims of the '403 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights.

100. Upon information and belief, the formulation of Aveva's ANDA product comprises components that perform substantially the same function, in substantially the same way, to achieve the same result as the claimed formulation. Upon information and belief, any differences between the formulation of Aveva's ANDA product and the asserted claims are merely insubstantial.

101. Upon information and belief, the Aveva Defendants have knowledge of the '403 patent and Aveva Drug Delivery Systems, Inc. has filed ANDA No. 217221 seeking authorization to commercially manufacture, use, offer for sale, and sell Aveva's ANDA Product in the United States. Upon information and belief, if the FDA approves ANDA No. 217221, physicians, health care providers, and/or patients will use Aveva's ANDA Product in accordance with the instructions and/or label provided by the Aveva Defendants and will directly infringe, either literally or through the doctrine of equivalents, one or more claims of the '403 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights.

102. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and the Aveva Defendants as to liability for the infringement of '403 patent claims. The Aveva Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from the Aveva Defendants' threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor as follows:

a) declare that the Asserted Patents are valid and enforceable;

b) declare that, under 35 U.S.C. § 271(e)(2)(A), the Aveva Defendants infringed the Asserted Patents by submitting ANDA No.217221 to the FDA to obtain approval to commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States Aveva's ANDA product prior to the expiration of the Asserted patents;

c) declare that the Aveva Defendants' commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Aveva's ANDA Product prior to the expiration of the Asserted Patents constitutes infringement of one or more claims of the Asserted Patents under 35 U.S.C. § 271 (a), (b), and/or (c);

d) order that the effective date of any FDA approval of Aveva's ANDA Product shall be no earlier than the expiration date of the Asserted Patents, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) enjoin the Aveva Defendants, and all persons acting in concert with the Aveva Defendants, from seeking, obtaining, or maintaining final approval of ANDA No. 217221 until the expiration of the Asserted Patents, including any exclusivities or extensions to which Plaintiffs are or become entitled;

f) enjoin the Aveva Defendants, and all persons acting in concert with the Aveva Defendants, from commercially manufacturing, using, offering for sale, or selling Aveva's ANDA Product within the United States, or importing Aveva's ANDA Product into the United States,

until the expiration of the Asserted Patents, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(B);

g) enjoin the Aveva Defendants, and all persons acting in concert with the Aveva Defendants, from commercially manufacturing, using, offering for sale, or selling Aveva's ANDA Product within the United States, or importing Aveva's ANDA Product into the United States, until the expiration of the Asserted Patents, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 283;

h) declare this to be an exceptional case and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4); and

i) grant Plaintiffs such further and additional relief that this Court deems just and proper.

Dated: June 22, 2022

By: */s/ John C. Carey*

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